

In re National Prescription Opiate Litigation: MDL 2804
Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Memorandum of Law in Opposition to Non-RICO Small Distributors' Motion for Summary Judgment Based on their *De Minimis* Status (DKT # 1879)

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Plaintiffs submit this memorandum in opposition to the summary judgment motion filed by Distributor Defendants Anda, Inc., H.D. Smith, Henry Schein, Inc., and Prescription Supply Inc., and affiliated entities. Despite a relatively small market share, these Defendants' conduct cannot be legitimately described as *de minimis*, as they claim in their Motion for Summary Judgment. Rather, the evidence reveals that each of the Defendants shipped massive quantities of opioids into Summit and/or Cuyahoga Counties. Each of their Suspicious Order Monitoring programs ("SOMs") was wholly deficient, allowing compliance to take a backseat to sales. Because of their deficient SOMs programs, each of the Defendants shipped opioids into Summit and Cuyahoga Counties which should have been flagged as suspicious. These shipments resulted in adverse consequences in Summit and/or Cuyahoga Counties. In many cases, the Defendants have admitted their misconduct and responsibility.

Substantial evidence, in the form of documents, depositions, and expert testimony, shows that a genuine dispute of material fact exists as to each of the Defendants' causal connection to the harms suffered by Summit and Cuyahoga Counties, and therefore Defendants' Motion should be denied.

Filing Date: June 28, 2019
Response Date: July 31, 2019
Reply Date: August 16, 2019

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

OPIATE LITIGATION

This document relates to:

Track One Cases

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO NON-RICO SMALL
DISTRIBUTORS' MOTION FOR SUMMARY JUDGMENT BASED ON
THEIR *DE MINIMIS* STATUS (DKT # 1879)**

July 31, 2019

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INTRODUCTION

Plaintiffs submit this memorandum in opposition to the summary judgment motion filed by Distributor Defendants Anda, Inc., H.D. Smith, Henry Schein, Inc., and Prescription Supply Inc., and affiliated entities, who collectively refer to themselves as “Small Distributors,” on the basis of their market share in Cuyahoga and Summit Counties. Defendants inaccurately describe their conduct as *de minimis*, relying only on market share data for support. To evaluate whether each Defendant’s conduct was both a cause-in-fact and proximate cause, one must look beyond the market share. For each of the Defendants, there is direct evidence that: they shipped massive quantities of opioids into Summit and/or Cuyahoga Counties; they had deficient Suspicious Order Monitoring programs (“SOMs”); their deficient SOMs programs resulted in adverse consequences in Summit and/or Cuyahoga Counties; and, in many cases, the Defendants have admitted their misconduct and responsibility. This evidence refutes the claim that their conduct was *de minimis*. Ultimately, whether each Defendants’ conduct is so insignificant as to preclude liability is a question for a jury. Substantial evidence, in the form of documents, depositions, and expert testimony, shows that a genuine dispute of material fact exists as to each of the Defendants’ causal connection to the harms suffered by Summit and Cuyahoga Counties, and therefore Defendants’ Motion should be denied.

STATEMENT OF FACTS

I. DEFENDANTS’ AGGREGATE CONDUCT IS NOT *DE MINIMIS*.

Defendants point to legal definitions of “*de minimis*” as “trifling, minimal,” or “so insignificant that a court may overlook it in deciding an issue or case.” *See* Non-RICO Small Distributors’ Motion for Summary Judgment Based on their De Minimis Status (DKT # 1879) (hereinafter “SDDs’ Brief”) at 3 (citing Black’s Law Dictionary 464 (8th ed. 2004)). Trying to paint the Small-Distributor Defendants’ (“SDDs”) conduct as *de minimis*, Defendants’ brief opens with several misstatements as to the market share of each of the SDDs, claiming *incorrectly* that none of the SDDs had more than a

■■■■ market share. In fact, whether looked at in the aggregate or individual, the SDDs' conduct was hardly *de minimis*.

A. The Volume of Opioids Shipped by the Small-Distributor Defendants into Summit and Cuyahoga Counties is not “*de minimis*.”

The SDDs collectively shipped ■■■■ ■■■■ of opioids into Cuyahoga County (■■■■ dosage units)¹ and ■■■■ cumulative total MMEs into Summit County (■■■■ ■■■■² between 2006 and 2014. Combined, the SDDs shipped ■■■■ MMEs (■■■■ dosage units) to these two Counties. This massive quantity of opioids cannot be considered *de minimis*. No reasonable jury would find that ■■■■ doses of opioids is “trifling, minimal,” or “so insignificant that a court may overlook it.” But this is exactly what the SDDs ask the Court to determine.

Looking at Dr. McCann's analysis of shipments into Cuyahoga and Summit from 2006-2014 by MME, or by dosage units, three of the four named Small-Distributor Defendants (Anda Inc., H.D. Smith, and Prescription Supply, Inc.) had market shares that exceeded ■■■■ either cumulatively over the 2006-2014 period, or for at least one of the years during that time period.³ Henry Schein did not exceed ■■■■ in any given year, but the facts presented below show that its conduct resulted in harm to Summit County, and therefore was not *de minimis*. Further, contrary to the SDDs' claims, nowhere in McCann's report does he describe the SDDs' share, either individually or collectively, as “*de minimis*.”⁴

¹ Ex. 1, Report of Craig J. McCann, Ph.D., C.F.A. Dkt. # 2000-14, Appendix 9, at 3779, 3783.

² Ex. 1, McCann Rep., Dkt. #2000-14, Appendix 9, at 3849, 3852.

³ Ex. 1, McCann Rep., Dkt. #2000-14, Appendix 9, at 3779, 3783, 3849, 3852.

⁴ In his deposition, Dr. McCann testified that “in some contexts ■■■■ would be *de minimus* [sic] and in other contexts not.” Ex. 2, Deposition of Craig J. McCann, May 10, 2019 at 509:12-22.

B. Defendants Shipped Massive Numbers of Suspicious Orders into Summit and Cuyahoga Counties.

In addition to the sheer quantity of opioids shipped into Summit and Cuyahoga Counties by the SDDs, the vast majority of the shipments should have been flagged as suspicious, and therefore not shipped unless an investigation cleared them. The expert report of Dr. Craig McCann reveals that from between 2006 and 2014, the SDDs shipped *at least* [REDACTED] MMEs and [REDACTED] doses of opioids in suspicious orders into the Track One Counties.⁵ Defendants' expansion of the supply of opioids – by shipping opioids that it knew, or should have known, were likely to be diverted – caused an escalation in the harmful effects of the opioid epidemic. As Plaintiffs' expert, Katherine Keyes, explains, “an additional consequence of the increased supply of opioids was an increase in the incidence and prevalence of non-medical opioid use and non-medical opioid use disorder in the general public.”⁶ Prescription opioids are diverted from the supply chain for sale and use in the black market.⁷ “[T]his non-medical use of opioids, stemming from diversion, has also contributed to the harm.”⁸

The aggregate shipment numbers for the SDDs in the bellwether Counties combined with the large numbers of flagged orders identified by Dr. McCann, are sufficient to create a genuine dispute of material facts as to whether the excess supply of opioids shipped by the SDDs in the bellwether

⁵McCann Rep., Dkt. #2000-14 at 59-76, Tables 24-33; Ex. 3, McCann Rep., Dkt. #2000-14, Appendix 10, at 307, 370, 532, 937, 1162. Defendants' factual analysis of McCann's flagged Orders for the SDDs is misleading. For example, Defendant includes an “n/a” in the row for Henry Schein, claiming, “Dr. McCann fails to identify any volume or ‘share’ of flagged orders attributable to Henry Schein.” SDDs' brief (Dkt #1879) at 8. Defendants do not explain that Henry Schein did not produce complete data to Plaintiffs, and therefore such an analysis was not possible. *See* McCann Rep., Dkt. #2000-14, at 29, fn 29. Further, because some of the SDDs did not distribute opioids during each of the years included in the Defendants' chart (indeed, HD Smith did not distribute opioids into Cuyahoga County until 2006), Defendants numbers are misleading.

⁶ Report of Katherine Keyes, Dkt. # 2000-9 at 18.

⁷ Keyes Rep., Dkt #2000-9 at 16-17.

⁸ *Id.* at 17.

Counties were diverted, resulting in harm.⁹ As the DEA stated in a 2006 letter to all CSA registrants, “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”¹⁰

Plaintiffs' expert witnesses used aggregate evidence to demonstrate the chain of causation.¹¹ James Rafalski and Craig McCann opined on the failures of distributors servicing Cuyahoga County and Summit County to maintain effective controls against diversion, which lead to an oversupply of opioids and diversion,¹² Jonathan Gruber's report establishes a direct, causal relationship between Defendants' shipments of, and the misuse and mortality from, prescription and illicit opioids,¹³ while David Cutler and Thomas McGuire's reports set forth the relationship between shipments and harms, sustained by the bellwether counties.¹⁴ Plaintiffs have produced sufficient aggregate evidence of causation to withstand the SDDs' Motion for Summary Judgment.

II. DEFENDANTS' INDIVIDUAL CONDUCT IS NOT *DE MINIMIS*.

In addition to the aggregate evidence, there is also evidence with respect to each of the SDDs causal link to the alleged injuries. Each of the SDDs shipped large quantities of opioids into Summit and Cuyahoga Counties; each had a flawed SOMs system; for each SDD, Plaintiffs have specific

⁹ The SDDs claim that any harm resulting from the shipments of opioids “would have occurred regardless of the [SDDs] conduct” because “█ of the opioids shipped to the Track One Counties still would have been shipped there in the absence of any one of the Small Distributor's shipments.” SDDs' Brief at 13. This misstates both the facts and the law. There were years where one or more of the SDDs had more than █ market share. For example, in 2006, Anda had a █% market share in Summit County. Ex 1, McCann Rep., Dkt. #2000-14, Appendix 9 at 3849. Whether or not the absence of █% of the supply of opioids from the market would have resulted in harm in Summit County is a question of disputed fact for the jury.

¹⁰ Ex. 4, US-DEA-00001767 at 2.

¹¹ See Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation (Dkt. #s 1869, 1897, and 1941), for a more detailed description of the expert reports.

¹² Report of James E. Rafalski, Dkt. # 2000-22 at 7; McCann Rep., Dkt. #2000-14 at 6. ¶ 20; Rafalski testified that if an order met the definition of a suspicious order, in his opinion it was probable (greater than 51%) that the order would be diverted. James Rafalski Dep. (05/13/19), Dkt. # 1969-18 at 189-190.

¹³ Report of Jonathan Gruber, Dkt. # 2000-6 at 8-9, 49.

¹⁴ Ex. 5, Report of David Cutler, Dkt. # 2000-4 at 6, ¶ 11, Appendix III.J, pp. 1-5; Report of Professor Thomas McGuire, Dkt. # 2000-17 at 6-7; Report of Professor Thomas McGuire, Dkt. # 2000-18 at 8.

evidence of particular instances in which their SOMS system didn't work as it was supposed to resulting in shipments to Summit and/or Cuyahoga County; and each SDD has admitted to its failures to prevent diversion, with some even admitting that they bear responsibility for the opioid crisis. There is, at the very least, a genuine dispute of material fact as to whether each Defendant's conduct was *de minimis*.

A. Anda

Between 2006-2014, Anda shipped a massive quantity of opioids into Cuyahoga County. ████████ MMEs, or ████████ doses,¹⁵ to be exact. From 2013 to 2014, Anda's shipments into Cuyahoga County increased by almost ████████. Dr. McCann's report identified as many as ████████ transactions shipped by Anda into Cuyahoga County between 1996-2018 which should have been flagged, using one of his five methods for flagging transactions.¹⁶ This translates into ████████ MMEs (████████ doses), or over ████████ of the opioids Anda shipped into Cuyahoga County.¹⁷

Between 2006-2014, Anda shipped ████████ MMEs, or ████████ doses, into Summit County.¹⁸ Anda had ████████% of the market share in 2006 and ████████ in 2007.¹⁹ For Summit County, Dr. McCann calculated that between 1996-2018, Anda had shipped in as many as ████████ transactions that should have been flagged.²⁰ These flagged transactions equate to ████████ MMEs and ████████ dosage units,²¹ both of which are well over ████████ of the total shipments of opioids Anda sent to Summit County during that time.²²

¹⁵ Ex. 1, McCann Rep., Dkt. #2000-14, Appendix 9, p. 3779, 3783.

¹⁶ McCann Rep., Dkt. #2000-14 at 75, Table 32.

¹⁷ Ex. 3, McCann Rep., Dkt. #2000-14, Appendix 10, p. 307.

¹⁸ Ex. 1, McCann Rep., Dkt. #2000-14, Appendix 9, pp. 3849, 3852.

¹⁹ Ex. 1, McCann Rep., Dkt. #2000-14, Appendix 9, p. 3849.

²⁰ McCann Rep., Dkt. #2000-14 at 76, Table 33.

²¹ Note that Dr. McCann's analysis of flagged orders covers the time 1996-2018, whereas the shipment numbers listed above are only from 2006-2014. This explains how the flagged order dosage numbers are larger than the overall shipment dosage numbers.

²² Ex. 3, McCann Rep., Dkt. #2000-14, Appendix 10, p. 937.

The sheer volume of opioids shipped into Cuyahoga and Summit Counties (over [REDACTED] MMEs and over [REDACTED] doses), and the incredibly high number of suspicious (“flagged”) orders (over [REDACTED] MMEs and over [REDACTED] doses) is sufficient to raise an inference that diversion and harm followed.

The fact that Anda had such a high percentage of opioids shipped into Summit and Cuyahoga Counties which it should have deemed suspicious, is evidence of a failed SOMs program. Anda’s SOMs program was deficiently designed and implemented in numerous ways, including: 1) Anda routinely shipped orders in excess of the monthly threshold it assigned customers, for which it was cited by the DEA;²³ 2) thresholds were routinely increased when a customer placed an order that exceeded the threshold;²⁴ 3) the new limit would become permanent, even if the reason for the increase was temporary;²⁵ 4) Anda shipped suspicious orders without reporting them to the DEA;²⁶ 5) Anda’s policy was to clear suspicious orders for a number of standard reasons which did not actually involve investigation;²⁷ and 6) Anda’s compliance department was severely understaffed.²⁸

Given these insufficient processes, it is not surprising that Anda’s opioids ended up being shipped to entities that they should not have been. Two examples in Ohio are illustrative.²⁹ First,

²³ Michael Cochrane Dep. (01/15/19), Dkt. #1961-1 at 215-216.

²⁴ Cochrane Dep., Dkt. # 1961-1 at 122-124 (obtaining a 3900% increase to 200,000 pills per opioid family per month; Ex. 6, Anda_Opioids_MDL_0000275048 (approving increase of 99,999% allowing “purchase up to unlimited dosage units per month; Ex. 7, Anda_Opioids_MDL_0000284363-4 (removing all thresholds and allowing unlimited purchases).

²⁵ See Ex. 8, Anda_Opioids_MDL_0000082872; Ex. 9, Deposition of Emily Schulz at 158:6-16.

²⁶ Between 2007 and 2012, Anda had not reported a single suspicious order to the DEA. Cochrane Dep., Dkt. # 1961-1 at 102-103, 233-234.

²⁷ The list of acceptable reasons suspicious orders could be cleared was vague, allowing clearance for just about any reason. See Ex. 10, Anda_Opioids_MDL_0000056015 (SOP 40). When the DEA told Anda in 2011 that it should start an on-site inspection program – it never did. Ex. 11, Anda_Opioids_MDL_0000133096.

²⁸ Anda’s compliance program had just 6 employees as compared to the 216 employees in the Sales Department. This means that each compliance officer would have to review 722 suspicious orders *per month* to keep up with the workload. Robert Brown Dep. (12/03/18), Dkt. # 1959-12 at 254:11-255:17; Ex. 12, Anda_Opioids_MDL_0000111939 at 9. Anda’s own documents evidence its failed SOMs program—in 2011 Anda had 9,624 customers without appropriate due diligence materials to whom Anda was still shipping opioids. Ex. 13, Anda_Opioids_MDL_0000601903; Ex. 14, Deposition of Sabrina Solis, p. 308-9.

²⁹ In addition to these examples, Plaintiffs have identified 20 exemplar shipments of suspicious orders sent by Anda into Summit and Cuyahoga Counties. See Ex. 15, Plaintiffs Response to Disc Ruling No 12 As Amended, p. 10 & 23.

when Walgreens' wholesaler had its distribution centers shut down, Anda became Walgreens' exclusive secondary distributor of Schedule II Controlled Substances in 2013, despite the fact that Anda had conducted an Audit of Walgreens showing that 75% of Walgreens' Ohio stores had red flags of diversion.³⁰ Second, when Lake Erie Medical (located just outside of Summit and Cuyahoga Counties) was admonished by the DEA for lacking suspicious order monitoring, Anda continued to approve huge shipments to Lake Erie.³¹ In fact, it repeatedly increased Lake Erie's thresholds (from 75,000 units per month per chemical, to 200,000 units per month).³² A jury could conclude that Anda's provision of opioids to a customer with a history of DEA compliance issues in such close proximity to Summit and Cuyahoga Counties,³³ resulted in opioid diversion and harm in those counties.

Anda's failures with respect to its SOMs program are all the more egregious because it knew the propensity for opioids to be abused, and that it had an obligation to take "reasonable measures" to identify suspicious orders and implement procedures that would ensure that its opioids were not being diverted for illicit use.³⁴ Instead of focusing on preventing diversion, Anda focused on sales.³⁵ Anda promoted various opioids to increase its sales numbers, while at the same time failing to implement an effective SOMs program.³⁶

³⁰ Ex. 16, Deposition of William Versosky, pp. 194-201; Brown Dep., Dkt. # 1959-12 at 141.

³¹ Cochrane Dep., Dkt. # 1961-1 at 186-197.

³² Cochrane Dep., Dkt. # 1961-1 at 186-197, Ex. 17, Anda_Opioids_MDL_0000276298; Ex. 18, Anda_Opioids_MDL_0000276293; Ex. 19, Anda_Opioids_MDL_0000273585.

³³ These are just two examples. Anda's relationship with Choice Pharmacy in Cuyahoga County is also alarming. After committing to the DEA in 2007 that it would cap controlled substances sales to its customers at 5,000 units per family, Anda allowed New Choice to purchase 20,000 units per opioid family. Albert Paonessa of Anda wrote that "the controls versus non-controls scare me," but he agreed to the increase and directed his staff to "see if we can legitimize it in some way." Ex. 20, Anda_Opioids_MDL_0000274587.

³⁴ Ex. 21, Anda_Opioids_MDL_0000338720; *see also* Ex. 22, Deposition of Albert Paonessa, p. 32-33.

³⁵ *See e.g.* Ex. 23, Anda_Opioids_MDL_0000077935 (requesting a new chain pharmacy customer be assigned the maximum allowable limit for all Level 2 Controlled Substances, explaining that if the chain is cut off from buying more [opioids], "it's going to hurt our relationship with the accounts"); Ex. 24, Anda_Opioids_MDL_0000618116 & Ex. 25, Anda_Opioids_MDL_0000629163 (pushing OxyContin sales to ensure profit).

³⁶ Brown Dep., Dkt. # 1959-12 at 166-168; Ex. 26, Deposition of Patricia Williams, p. 126; Ex. 27, Anda_Opioids_MDL_0000634359.

Finally, Anda has admitted that it is to blame for the opioid related harm: “Is the one who makes the drugs, sells the drugs, prescribes the drugs, or fills a prescription for the drug [to blame]? We all play a very important role and that is why we are all responsible.”³⁷

The above evidence shows that there is a genuine dispute of material fact with respect to whether Defendant Anda’s conduct was a factual and legal cause of the harms alleged by Plaintiffs, despite Anda’s allegedly *de minimis* market share. Defendant Anda’s Motion for Summary Judgment should therefore be denied.

B. Henry Schein

Distributor Defendant Henry Schein, Inc. (“HS”) is one of the largest direct sellers of products (including controlled substances) to dental, orthodontic, and primary care physicians in the United States. HS is ranked #238 on the Fortune 500 and had global net sales of \$12.5 billion in 2017. Unlike the other Distributor Defendants in CT1, HS sold opioids directly to their doctor and dental customers in Summit County.³⁸

Between 2006-2014, HS shipped [REDACTED], or [REDACTED] doses, of opioids into Summit County.³⁹ Because HS supplied insufficient information in discovery, Dr. McCann was not able to calculate the amount of orders HS should have flagged. However, diversion is the expected result of insufficient SOMs programs, of which there is ample evidence.

Plaintiffs’ expert, James E. Rafalski, offered several critiques of HS’s SOMs program, concluding that “historically the due diligence conducted by [HS] has been inadequate, [HS’s] due diligence efforts have fallen short of what is required,” and “[HS] has admitted that it lacked complete due diligence files for all of its customers until at least 2017.”⁴⁰ These critiques are backed up by

³⁷ Ex. 21, Anda_Opioids_MDL_0000338720.

³⁸ Henry Schein was named as a Defendant in the Summit County Complaint; it is not named in the Cuyahoga County Complaint.

³⁹ Ex. 1, McCann Rep., Dkt. 2000-14, Appendix 9 at 3849, 3852.

⁴⁰ Rafalski Rep., Dkt # 2000-22 at 142-145.

substantial documentary evidence and deposition testimony in the record, which show that: 1) for decades, HS detected suspicious orders based upon deviations in size only, they didn't take into account frequency or pattern;⁴¹ 2) for over a decade, HS did not report any suspicious orders to the DEA;⁴² 3) when it did report, it would do so monthly, after the order was shipped, rather than immediately reporting it to the DEA;⁴³ 4) at various points in time, when an order was flagged, the entire due diligence process involved sending the customer a one page questionnaire, there was no on-site interview and the results of the "investigations" were not documented;⁴⁴ 5) HS lacked a written SOP relating to its "Know Your Customer" due diligence obligations until 2012;⁴⁵ and 6) HS lacked due diligence documents for 27,000 customers as of August 2013, in November 2013 they still lacked these documents for 60% of their customers."⁴⁶ In a November 9, 2012, letter to the Ohio Board of Pharmacy, HS admitted to under reporting sales of controlled substances (including a failure to report any sales of hydrocodone) in Ohio from at least 2010 to 2012, in violation of state law.⁴⁷ Finally, between 2009 and July 2019, HS never reported any suspicious orders in Summit County to the DEA.⁴⁸

⁴¹ See Shaun Abreu Dep. (12/13/18), Dkt # 1956-2 at 237:21-239:1; Ex. 28, Deposition of Michael DiBello at 181:12-182:17. See also Rafalski Rep., Dkt #2000-22 at 139.

⁴² See Ex. 29, HSI-MDL-00404203 at 205; Rafalski Rep., Dkt # 2000-22 at 142.

⁴³ See Jeff Peacock Dep. (01/30/19), Dkt # 1969-4 at 153:1-24; Ex. 28, DiBello Dep. at 157:9-159:10; 267:9-270:12; Abreu Dep., Dkt # 1956-2 at 51:18-53:18, 55:12-57:23; 64:11-67:13; 71:4-73:21; 83:10-21; 146:15-148:16; Ex. 30, Deposition of Sergio Tejada at 318:5-320:7; 330:24-331:12.

⁴⁴ Rafalski Rep., Dkt # 2000-22 at 139, 144.

⁴⁵ Rafalski Rep., Dkt #2000-22 at 144.

⁴⁶ Rafalski Rep., Dkt #2000-22 at 144; Abreu Dep., Dkt # 1956-2 at 294:21-295:7; 308:10-310:24; Ex. 31, Deposition of Tina Steffanie-Oak at 74:9-78:1; 98:15-20; 133:13-134:17; 135:10-22; 144:24-145:9; 149:15-150:21; Ex. 30, Tejada Dep., at 222:6-16; 225:11-227:9; 232:11-15; 233:14-234:15; 248:23-249:3. HS acknowledged that they would need three to four years to become "current/fully compliant with DEA due diligence." Rafalski Rep., Dkt # 2000-22 at 144.

⁴⁷ See Ex. 32, HSI-MDL-00397293-294 and Ex. 30, Tejada Dep. at 158:11-164:10.

⁴⁸ Rafalski Rep., Dkt # 2000-22 at 143.

As a result of these SOMs failures, HS shipped opioids to Summit County that ended up being diverted. For example,⁴⁹ Dr. Adolph Harper was HS's largest customer in Summit County; his diversion of opioids provided to him by HS resulted in at least eight deaths, and he was sentenced to ten years in prison.⁵⁰ In 2012 he surrendered his license after state and federal authorities determined he was illegally prescribing opioids and operating a pill mill.⁵¹ In 2014, he pled guilty to counts that included conspiracy to traffic drugs, health care fraud, and sixteen counts of drug trafficking.⁵²

HS's second largest customer in Summit County was Dr. Brian Heim, to whom HS supplied 11,500 tablets of hydrocodone over an eleven-month period from August 2011 through June 2012 (the same time frame in which HS failed to report hydrocodone sales to the OH Board of Pharmacy) without performing basic due diligence.⁵³ Heim had previously pled guilty in 1998 in Ohio state court to twenty-four felony counts of theft of drugs and he had his medical license revoked and then later reinstated in 2005. During the period of 2011-2012 (when HS sold him hydrocodone), Heim was actually under indictment in Ohio state court for trafficking in drugs (specifically, drugs supplied by HS) and tampering with evidence.⁵⁴ The sheer volume of Dr. Heim's purchases from HS was so suspicious that the DEA got involved.⁵⁵ Yet HS never reported any of Heim's orders as suspicious to the DEA, and it never refused to ship an order to Dr. Heim.⁵⁶

The evidence presented above is sufficient to create a genuine dispute of material fact that HS sent opioids into Summit County that never should have been shipped there, and as a result, there

⁴⁹ Plaintiffs have identified 14 exemplar shipments of suspicious orders sent by HS to Dr. Heim in Summit County. See Ex. 15, Plaintiffs Response to Disc Ruling No 12 As Amended, p. 33.

⁵⁰ Ex. 30, Tejada Dep. at 143-147.

⁵¹ Report of Lacey Keller, Dkt. # 2000-7 at 46.

⁵² Keller Rep., Dkt. # 2000-7 at 47.

⁵³ Ex. 30, Tejada Dep. at 167-180; Abreu Dep., Dkt. # 1956-2 at 317-376, 417.

⁵⁴ *Id.* See also Ex. 33, Peacock Dep., Dkt. # 1969-4 (Exhibit 20 to Peacock Dep); Ex. 34, Abreu Dep., Dkt. # 1956-2, (Exhibit 19 to Abreu Dep) at 5-6.

⁵⁵ Ex. 34, Abreu Dep., Dkt. # 1956-2 (Exhibit 19 to Abreu Dep) at 5-6.

⁵⁶ Abreu Dep., Dkt. # 1956-2 at 333-340.

was harm sustained. Because there is a genuine issue in dispute, HS's Motion for Summary Judgment should be denied.

C. HD Smith⁵⁷

Between 2006-2014, H.D. Smith shipped [REDACTED] MMEs, or [REDACTED] doses of opioids into Cuyahoga County.⁵⁸ From 2010-2014, H.D. Smith had more than a [REDACTED] market share in Cuyahoga.⁵⁹ From 2008 to 2009, H.D. Smith's shipments into Cuyahoga County increased by almost 2,000%. Dr. McCann's report identified as many as [REDACTED] shipped by H.D. Smith into Cuyahoga County between 1996-2018, which should have been flagged, using his five methods for flagging transactions.⁶⁰ This translates into [REDACTED] ([REDACTED] doses) that H.D. Smith shipped into Cuyahoga County which should have been investigated as suspicious.⁶¹ Further, Dr. McCann's report details the ways in which the ARCOS data and the H.D. Smith data are missing substantial amounts of information, making Dr. McCann's estimate conservative.⁶²

H.D. Smith's SOMs system was deficient in a number of ways, making the diversion of some of the opioids H.D. Smith shipped into Cuyahoga County foreseeable. The deficiencies included: 1) from 2006 through 2008, H.D. Smith had a manual, rather than automated SOM program; 2) reports which might have identified suspicious orders were not reviewed until after the orders had shipped; 3) the "thresholds" (also called "Upper Reportable Limits" or "URLs" at H.D. Smith) were based on the client's prior sales – in other words, the more the client spent, the higher their limit was set; 4) the SOMs policy gave each new customer a 90-120 day ordering period during which time it

⁵⁷ H.D. Smith is named only in the Cuyahoga Complaint, not in the Summit County Complaint.

⁵⁸ Ex. 1, McCann Rep., Dkt. # 2000-14, Appendix 9, pp. 3779, 3783.

⁵⁹ Ex. 1, McCann Rep., Dkt. # 2000-14, Appendix 9, pp. 3779.

⁶⁰ McCann Rep., Dkt. # 2000-14 at 63.

⁶¹ Ex. 3, McCann Rep., Dkt. # 2000-14, Appendix 10, p. 370.

⁶² McCann Rep., Dkt. # 2000-14 at 42-43.

had no limits on numbers of opioids it ordered;⁶³ 5) H. D. Smith also notified customers when they approached their threshold limits, allowing the customer to request an increase and avoid reporting suspicious orders to the DEA;⁶⁴ 6) [REDACTED]

[REDACTED]⁶⁵.and 7) [REDACTED]
[REDACTED]

In fact, H.D. Smith employees have admitted on numerous occasions that their SOMs program was not sufficient to prevent the diversion of opioids. For example, George Euson, Director of Compliance and Security, said “We will have a hard time explaining to DEA why after we were warned nearly 1 ½ years ago, we continued to sell excessive quantities of CS to these businesses,”⁶⁷ and that “[i]n most cases the customer will not be reported to DEA as suspicious, except in extreme cases.”⁶⁸ Another H.D. Smith employee advised in October 2013 that HD Smith still had no Order Monitoring System in place and that she had serious concerns regarding this as HD Smith was “absolutely not compliant with Federal Regulations” and “we know we aren’t.”⁶⁹ Internal emails show that in May 2014, there was a [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]⁷⁰ In a February

⁶³Ex. 35, HDS_MDL_00185721; Ex. 36, HDS_MDL_00171736; Ex. 37, HDS_MDL_00185888; Ex. 38, HDS_MDL_00438407; Ex. 39, HDS_MDL_00332594; Ex. 40, HDS_MDL_00193305-3306; Ex. 41, HDS_MDL_00408717; George Euson Dep., Dkt # 1961-24 at 153-155.

⁶⁴Ex. 42, HDS_MDL_00193790.

⁶⁵Ex. 43, HDS_MDL_00408622.

[REDACTED]
[REDACTED]
⁶⁷Ex. 46, HDS_MDL_00136622.

⁶⁸Ex. 47, HDS_MDL_00178075. In a 2014 Compliance presentation, H.D. Smith reported that they had reported only 0.15% of the suspicious orders they had received. Ex. 48, HDS_MDL_00387737.

⁶⁹Ex. 49, HDS_MDL_00394078.

⁷⁰Ex. 50, HDS_MDL_00401985.

2015 exit interview, a compliance employee quit because, among other things, “she believes the company is and has been breaking the law for some time.”⁷¹

In light of these admitted failures, it is not unreasonable to assume that H.D. Smith’s opioids might end up being diverted in Cuyahoga County, and in fact, they were.⁷² One of H.D. Smith’s primary customers in Cuyahoga County was [REDACTED] orders repeatedly hit H.D. Smith’s SOMs program, but were shipped without investigation, even when they exceeded the thresholds.⁷³ H.D. Smith never reported any of [REDACTED] orders as suspicious to the DEA.⁷⁴ Instead, H.D. Smith increased [REDACTED] URL, to ensure that its account would never hit the SOM program.⁷⁵ Plaintiffs’ expert, Lacey Keller, identified [REDACTED] as one of the pharmacies in Cuyahoga County where “opioids were being used problematically and where diversion was a concern.”⁷⁶ Further, Plaintiffs’ expert, James Rafalski testified in his deposition that if it met one of his suspicious order tests, in his opinion, the chance of diversion occurring was greater than 51%.⁷⁷

The evidence presented above is sufficient to create a genuine dispute of material fact that H.D. Smith sent opioids into Cuyahoga County that never should have been shipped there, and as a result, there was harm sustained. Because there is a genuine issue in dispute, H.D. Smith’s Motion for Summary Judgment should be denied.

⁷¹Ex. 51, HDS_MDL_00510236.

⁷² In addition to the above, Plaintiffs have identified 10 exemplar shipments of suspicious orders sent by H.D. Smith into Cuyahoga County. See Ex. 15, Plaintiffs Response to Disc Ruling No 12 As Amended, p. 15.

⁷³Euson Dep., Dkt # 1961-24 at 189; Ex. 52, HDS_MDL_00091981.

⁷⁴Euson Dep., Dkt # 1961-24 at 186.

⁷⁵Ex. 53, HDS_MDL_00006276; Ex. 52, HDS_MDL_00091981; Ex. 54, HDS_MDL_00038924.

⁷⁶Keller Rep., Dkt # 2000-7 at 12.

⁷⁷Rafalski Dep. (05/13/19), Dkt # 1969-18 at 189-190.

D. Prescription Supply, Inc.

Prescription Supply, Inc. (“PSI”) is a family-run business that has been engaged in the wholesale distribution of pharmaceuticals since 1955.⁷⁸ Today, it is a DEA-licensed wholesale distributor involved in pharmaceutical sales across an estimated thirty states.⁷⁹

Between 2006-2014, PSI shipped [REDACTED] MMEs, or [REDACTED] doses of opioids, into Cuyahoga County.⁸⁰ In 2006-2009, PSI had more than a 1% market share in Cuyahoga County, ranging from 1.8%-2.7%.⁸¹ Dr. McCann’s report identified as many as [REDACTED] transactions shipped by PSI into Cuyahoga County between 1996-2018 which should have been flagged as suspicious.⁸² This translates into [REDACTED] (2,462,130 doses), or over [REDACTED] of the opioids PSI shipped into Cuyahoga County.⁸³

Between 2006-2014, PSI shipped [REDACTED] and [REDACTED] doses of opioids into Summit County.⁸⁴ For Summit County, Dr. McCann calculated that PSI had shipped in 21 transactions that should have been flagged.⁸⁵ These flagged transactions equate to [REDACTED] MMEs and [REDACTED] dosage units, both of which are around [REDACTED] of the total shipments of opioids PSI sent to Summit County.⁸⁶

The sheer volume of suspicious (“flagged”) orders that were shipped into Cuyahoga and Summit Counties by PSI is sufficient to raise an inference that diversion and harm followed. However, there is additional evidence to support such an inference. In particular, PSI’s lack of a functional SOMs system leads to an inference of diversion.

⁷⁸ Deposition of Candace Harbauer (02/19/19), Dkt. # 1962-17 at 12:11-18; 19-7:5; 13:12-21.

⁷⁹ Harbauer Dep., Dkt. # 1962-17 at 15:15-16:4

⁸⁰ Ex. 1, McCann Rep., Dkt # 2000-14 at 3779, 3792, Appendix 9.

⁸¹ Ex. 1, McCann Rep., Dkt # 2000-14 at 3779, Appendix 9.

⁸² McCann Rep., Dkt # 2000-14 at 75.

⁸³ Ex. 3, McCann Rep., Dkt # 2000-14 at 532 of Appendix 10.

⁸⁴ Ex. 1, McCann Rep., Dkt # 2000-14 at 3849, 3852 of Appendix 9.

⁸⁵ McCann Rep., Dkt. # 2000-14 at 76.

⁸⁶ Ex. 3, McCann Rep., Dkt. # 2000-14 at 1162 of Appendix 10.

It was not until 2000 that PSI even had any written policy regarding SOMs.⁸⁷ When PSI did create guidelines in 2000, it did not include a policy to stop the shipment of suspicious orders.⁸⁸ Even after explicit communication from the DEA reiterating wholesale distributors' duty not to ship suspicious orders, PSI never adopted such a policy.⁸⁹ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁹⁰

In addition to failing to create a system that maintained effective controls against diversion, the undisputed evidence produced by PSI indicates that it never reported suspicious orders of opioids to the DEA, and it shipped suspicious orders of opioids without conducting any due diligence to dispel the suspicion of diversion from May of 1997 until 2013.⁹¹ In fact, PSI admitted as much when it's 30(b)(6) representative, Thomas Schoen, testified that the company received suspicious orders and that those orders were never reported to the DEA.⁹² When asked how many suspicious orders H.D. Smith had reported since 2013, PSI's Controlled Substance Handler responded, "zero."⁹³ This testimony is also consistent with the Ohio Board of Pharmacy's letter to PSI in October of 2017 noting that PSI had not reported a suspicious order to the Board during at least the years of 2014, 2015, 2016, and 2017.⁹⁴

⁸⁷ Harbauer Dep., Dkt. # 1962-17 at 82:10-17.

⁸⁸ Harbauer Dep., Dkt. # 1962-17 at 70:4-9, 94:22-95:3, and 81:4-82:9; 85:10-86:4. Kirk Harbauer Dep. (02/27/19), Dkt. # 1962-18 at 98:22-99:2.

⁸⁹ Harbauer Dep., Dkt. # 1962-17 at 107:24-108:8; 109:12-111:15.

⁹⁰ Ex. 55, PSI0000653; James Schoen Dep., (02/27/19), Dkt. # 1970-16 at 47:8-16; 42:4; 80:10-81:1.

⁹¹ Harbauer Dep., Dkt. # 1962-18 at 98:22-99:2; Thomas Schoen Dep., (09/05/18), Dkt. # 1970-17 59:11-60:2; Schoen Dep., Dkt. # 1970-16 at 121:17-123:5.

⁹² Schoen Dep., Dkt # 1970-17 at 183:23-184:3, 150:15-17.

⁹³ Schoen Dep., Dkt. #1970-16 at 115:19-116:2.

⁹⁴ Ex. 56, PSI0000009.

PSI's insufficient SOMs procedures lead to their distribution of opioids despite evidence of diversion. For example, deposition testimony reveals that PSI shipped opioids to a pharmacist in Cuyahoga County, even after the pharmacist had lost his license, assaulted a Board of Pharmacy Agent investigating his pharmacy, and was indicted on seven counts of illegal processing of drug documents and eight counts of trafficking.⁹⁵

The sheer volume of suspicious ("flagged") orders that were shipped into Cuyahoga and Summit Counties, is sufficient to raise an inference that diversion and harm followed. Likewise, the substantial evidence that PSI failed to implement an effective policy to prevent diversion is sufficient for a jury to conclude that PSI's failures led to diversion and harm in the bellwether Counties. Indeed, there is also direct evidence of diversion. Because genuine disputes as to material facts exist, Defendant PSI's Motion for Summary Judgment should be denied.

ARGUMENT

I. LEGAL STANDARD FOR CAUSATION.

The moving party has the burden of showing that no genuine dispute exists as to any material fact. *Hickle v. Am. Multi-Cinema, Inc.*, 927 F.3d 945, 951 (6th Cir. 2019). Summary judgment must be denied "if a reasonable jury could return a verdict for the nonmoving party[.]" *Kolesar v. Allstate Ins. Co.*, No. 1:19 CV 35, 2019 WL 2996047, at *2 (N.D. Ohio July 9, 2019) (Polster, J.) (citing *Baynes v. Cleland*, 799 F.3d 600, 606 (6th Cir. 2015)). In making this determination, "the court must view the facts and any inferences reasonably drawn from them in the light most favorable to the nonmoving party." *Id.* (citing same). Courts do not weigh the evidence or otherwise engage in "jury functions" in deciding a motion for summary judgment; "[i]f there remains any material factual disagreement as to a particular legal claim, that claim must be submitted to a jury." *Hickle*, 927 F.3d at 951 (citing *Bobo v. United Parcel Serv., Inc.*, 665 F.3d 741, 748 (6th Cir. 2012)).

⁹⁵ Schoen Dep., Dkt. # 1970-17 at 234:4-237:12; Ex. 57, PSI 0003419 (Ex 28 to T. Scheon Dep).

As explained at length in Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation (Dkt. #s 1869, 1897, and 1941), in order to establish causation, a plaintiff need only show that a defendant's wrongful conduct caused some harm and was a substantial factor in causing that harm. Moreover, as set forth in that brief, a plaintiff may rely both on the inference that a defendant's misconduct was the cause of the plaintiff's harm where the injury to plaintiff was the type of injury that defendant's conduct would be expected to cause, and also on aggregate proof of causation presented through the testimony of experts employing scientifically valid and reliable methodologies. In that Opposition, Plaintiffs explain that the injuries caused by diverted opioids are precisely the harms that would be expected to flow from Defendants' nonexistent or inadequate SOMs systems, and Plaintiffs demonstrate this causal connection through statistical analysis of aggregate evidence by their prominent public health economist experts. Plaintiffs here adopt and incorporate by reference pages 33-39 (Legal Standard for Causation), pages 43-52 (Aggregate Proof), pages 57-58 (Public Nuisance) of that brief.

II. THE SMALL DEFENDANT DISTRIBUTORS' MISCONDUCT (INDIVIDUALLY AND IN THE AGGREGATE) WERE A SUBSTANTIAL FACTOR IN CAUSING THE INJURIES SUFFERED BY PLAINTIFFS.

Plaintiffs have presented evidence that: 1) each SDD had an insufficient SOMs policy; 2) because of their insufficient SOMs policies, each SDD shipped opioids into Summit and/or Cuyahoga County that should not have been shipped; and 3) diversion of those shipments (both individually and in the aggregate) caused harm in Summit and Cuyahoga Counties. Therefore, there is a genuine dispute of material fact as to whether each SDDs' insufficient SOMs policy and subsequent shipments (the wrongful conduct) was a substantial factor in causing the harms alleged in Summit and Cuyahoga Counties.

Defendants have focused extensively on but-for causation in their brief, claiming essentially that the SDDs market share in Summit and Cuyahoga Counties were too small to be considered the

“but-for” cause of the opioid epidemic. This is the wrong standard. Plaintiffs need not prove that each Defendant caused the entirety of the harm. Under the substantial factor test, Plaintiffs need only create a genuine dispute of material fact as to whether “each defendant’s wrongful conduct caused *some* harm.” Restatement (Second) of Torts § 431, comment b (1965)(emphasis added). The numerous examples of excess shipments being diverted in Cuyahoga and Summit Counties, along with the expert testimony of Professor Thomas McGuire, satisfy that burden.⁹⁶

Defendants also challenge legal (proximate) cause; relying on the same argument they made for causation-in-fact, that their market share was too small to be the proximate cause.⁹⁷ This argument is without merit. Again, Defendants look only at market share, rather than at raw data. Plaintiffs have presented evidence that the SDDs shipped huge volumes of suspicious orders into Summit and Cuyahoga Counties. These shipments were made without the proper due diligence. As a result, diversion occurred, causing harm to the Plaintiffs. The Controlled Substances Act requires Distributors to have SOMs programs to avoid this exact scenario. In other words, Plaintiffs suffered just the “sort of injury that would be the expected consequence of the defendant’s wrongful conduct,” and as a result, Plaintiffs have met their burden with respect to proximate/legal cause. *Empire Title Services, Inc. v. Fifth Third Mortg. Co.*, N.D. Ohio No. 1:10CV2208, 2013 WL 1337629, *9 (“Once a

⁹⁶Alternative tests for causation-in-fact have been employed in situations like this involving multiple tortfeasors. In *Paroline v. U.S.*, the Supreme court found that an individual possessor of child pornography was a cause-in-fact of harm to the victim because he participated in the collective wrongdoing which was a but-for cause of the victim’s harm. 572 U.S. 434, 452 (2014). The Court reasoned, “it would be nonsensical to adopt a rule whereby individuals hurt by the combined wrongful acts of many (and thus in many instances hurt more badly than otherwise) would have no redress, whereas individuals hurt by the acts of one person alone would have a remedy. These are the principles that underlie the various aggregate causation tests the victim and the Government cite, and they are sound principles.” Under this test, there can be no doubt that each of the SDDs’ conduct was a cause-in-fact of the harm, because they participated in the collective wrongdoing of all the Defendants, which was a but-for cause of the opioid epidemic in Summit and Cuyahoga Counties.

⁹⁷ Defendants cite to *Schwartz v. Honeywell Int’l, Inc.*, 102 N.E.3d 477, 482 (Ohio 2018) for the contention that to be a “substantial factor” in situations involving “total cumulative exposure,” a single exposure cannot be considered a “substantial cause unless that exposure...had a substantial impact.” However, *Schwartz* was an asbestos injury case interpreting what “substantial factor” meant under the state’s asbestos statute (R.C. 2307.96), and the Restatement itself does not require that there be a “substantial impact” in order for conduct to be a “substantial factor.”

plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation.”).

To establish proximate cause under the substantial factor test, Plaintiffs must show a genuine dispute as to whether the effect of Defendants’ conduct is “substantial,” meaning “more than merely negligible.” Restatement (Second) of Torts § 431, comment b (1965). Plaintiffs have established, or at the very least created a genuine dispute of material fact, that the harms suffered by Summit and Cuyahoga Counties (opioid overdoses, child removals due to opioid addiction, etc.)⁹⁸ as a result of Defendants’ conduct are more than “merely negligible.” Because the “determination of whether an actor's conduct was a substantial factor in producing the plaintiff's injury is a question of fact to be determined by the trier of fact” Defendants’ Motion for Summary Judgment should be denied. *Queen City Terminals, Inc. v. Gen. Am. Transp. Corp.*, 73 Ohio St.3d 609, 1995-Ohio-285, 653 N.E.2d 661 (1995); *see also Baldridge v. Wright Gas Co.*, 154 Ohio St. 452, 96 N.E.2d 300, 304 (1951) (“[C]ausation is for the determination of the jury and it is not for the court to substitute its reasoning for that of the jury in a field which belongs peculiarly to the latter.”). *See also Brown v. Wal-Mart Stores, Inc.*, 198 F.3d 244 (6th Cir.1999) (Sixth Circuit allows jury to infer causation where harm to plaintiff—injury from item falling from overhead riser—was the expected consequence of Walmart’s negligence of failing to adhere to safety guidelines for stocking shelves).

With public nuisance, Plaintiffs must demonstrate that the Defendants’ conduct was a substantial contributing factor to the *nuisance*, (as opposed to any specific injuries.). Defendants’ argue that their market share was too small for it to have been a substantial contributing factor to the nuisance. Defendants’ argument fails. Plaintiffs meet this burden through the same evidence that

⁹⁸ See McGuire Rep., Dkt # 2000-17 at 7-8.

applies to all their claims: expert opinion, aggregated and individual proof and the conduct and admissions of Defendants. It is a disputed question of material fact whether these shipments were a substantial factor in contributing to the public nuisance in Plaintiffs' communities. *See, e.g.,* McGuire Expert Report on Public Nuisance, pp. 21-53 ("Shipments of Prescriptions Constituted a Public Nuisance to the Bellwether Communities"); Motion of Plaintiffs Cuyahoga And Summit Counties For Partial Summary Adjudication Of Their Equitable Claims For Abatement Of An Absolute Public Nuisance (June 28, 2019) (laying out, in detail, how the opioid epidemic is an ongoing public nuisance in Cuyahoga and Summit Counties given the effect on health and safety); *In re Nat'l Prescription Opiate Litig.*, 2019 U.S. App. LEXIS 18502, at *3-4 (6th Cir. June 20, 2019) ("the circumstances in this case, which affect the health and safety of the entire country, are certainly compelling."). This is all that is needed for Plaintiffs to satisfy their burden to survive summary judgment on their public nuisance claims.

Simply repeating the phrase "Defendant's conduct is *de minimis*," does not make it true. Market share numbers do not tell the story of Defendants' conduct. To get a sense of the true impact of the SDDs' conduct, one must look at: 1) the quantity of opioids shipped into the bellwether Counties - [REDACTED] MMEs ([REDACTED] dosage units); 2) the volume of flagged orders shipped into the bellwether Counties - [REDACTED] MMEs and [REDACTED] dosage units; 3) the numerous deficiencies for each of the SDDs' SOMs policies; and 4) the examples of diversion of opioids shipped by Defendants in the bellwether Counties.⁹⁹ By looking at these factors, it is evident that the SDDs'

⁹⁹ Defendants claim that the Plaintiffs' expert reports "largely ignore" the SDDs, and neatly conclude that this means the SDDs conduct is *de minimis*. As described in depth, Plaintiffs' experts have not ignored the SDDs, and even if they had, this is not dispositive. While it is well-accepted in the Sixth Circuit and Ohio that expert testimony can establish causation at the summary judgment stage, a plaintiff's showing of causation at the summary judgment stage can be supplemented, and even satisfied by other forms of circumstantial evidence. *See, e.g., Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 269 (6th Cir. 2001) ("We also recognize that even without expert testimony on the specific question of causation, Plaintiff adduced sufficient evidence to demonstrate a causal connection . . ."). The combination of the expert evidence, even in aggregate form, with circumstantial evidence is enough to create a jury question on causation. *In re Neurontin Mktg. & Sales Practices Litig. (Harden)*, 712 F.3d 60, 68 (1st Cir. 2013). *See also In re Neurontin Mktg. & Sales Practices Litig. (Aetna)*, 712 F.3d 51, 58 (1st Cir. 2013) ("[Plaintiff's] evidence of but-for causation included not only aggregate statistical evidence, but

conduct cannot be considered “trifling, minimal,” or “so insignificant that a court may overlook it in deciding an issue or case.”

It is only by ignoring the above listed factors that the SDDs claim their conduct was “*de minimis*.” Because there is a genuine dispute as to whether the SDDs’ conduct is in fact *de minimis*, summary judgment must be denied. *See, e.g., Bell v. Johnson*, 308 F.3d 594, 603-04 (6th Cir. 2002)(“in most cases, the question of whether an alleged retaliatory action poses a sufficient deterrent threat to be actionable [i.e., is not *de minimis*] will not be amenable to resolution as a matter of law...[U]nless the claimed [conduct] is truly ‘inconsequential,’ the plaintiff’s claim should go to the jury.”); *Davidson v. Chestnut*, 193 F.3d 144, 150 (2d Cir. 1999) (noting that question of defendant’s conduct was *de minimis* was “factual in nature”); *Brennan v. Arctic Fur Co.*, No. C 1 74-198., 1975 U.S. Dist. LEXIS 14233, at *3 (S.D. Ohio Jan. 22, 1975) (denying summary judgment because whether an activity is “*de minimis* is a question of fact”); *Lacy v. Reddy Elec. Co.*, No. 3:11-cv-52, 2013 U.S. Dist. LEXIS 97718, at *33 (S.D. Ohio July 11, 2013) (denying summary judgement because there was a “question of fact as to whether the time spent on these activities was *de minimis*.”); *Adoption Of J.P.E. & A.A.E.*, 2017-Ohio-1108, ¶ 13 (Ct. App.) (it is a factual question of whether the natural parent failed to have more than *de minimis* contact with the child); *Hanna v. Redlin Rubbish Removal, Inc.*, C.A. NO. 15280, 1992 Ohio App. LEXIS 1773, at *6 (Ct. App. Apr. 1, 1992) (noting that even a “*de minimis*” error may have a “substantial impact.”); *Rudner v. Abbott Labs., Inc.*, 664 F. Supp. 1100, 1107 (N.D. Ohio 1987) (noting whether sales were *de minimus* [sic] is a fact question).¹⁰⁰ In light of the facts presented, it

circumstantial evidence It should have been left to a jury to weigh the aggregate and circumstantial evidence of causation”). Here Defendants’ own admissions, detailed in the fact section, can support a showing of causation. *See In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 810 (N.D. Ohio 2004), *aff’d sub nom. Meridia Prod. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006).

¹⁰⁰ The cases cited by Defendants in support of their *de minimis* argument are distinguishable. Many of the cases cited do not examine whether the Defendants’ *conduct* was *de minimis*, but rather whether Plaintiff’s *injuries* were *de minimis*. *See, e.g. Baker v. Chevron USA Inc.*, 533 F. App’x 509, 524 (6th Cir. Aug. 2, 2013) (holding that a gasoline odor on the plaintiffs’ property was a “*de minimis*” interference with their property and therefore not compensable. *Id.* at 524.); *Smith v. Carbine and Chems. Corp.*, 507 F.3d 372, 380-81 (6th Cir. 2007)(“there is liability for nuisance only to those to whom it causes

cannot credibly be argued that the SDDs' conduct, or Summit and Cuyahoga's injuries, are trifling, minimal, or insignificant.¹⁰¹

CONCLUSION

For the foregoing reasons, this Court should deny Defendants' Motion for Summary Judgment.

Dated: July 31, 2019

Respectfully submitted,

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significant harm...By significant harm is meant harm of importance, involving more than slight inconveniences or petty annoyance. The law does not concern itself with trifles..." (Citing Restatement (Second) of Torts § 821F and §821F cmt. c)).

Other cases are distinguishable on their facts or their holding. See, e.g. *Byers v. Lincoln Elec. Co.*, 607 F. Supp. 2d 840, 860 (N.D. Ohio 2009)(Plaintiff failed to present evidence that they were exposed to more than ambient levels of asbestos); *Birnie v. Elec. Boat Corp.*, 953 A.2d 28, 41 (Conn. 2008) ("substantial," however, does not connote that the [defendant] must be the major contributing factor in bringing about the injury," and describing substantial factor as "[n]ot the sole factor, nor the predominant factor"); *New Jersey Dep't of Env'tl. Protection v. Ventron Corp.*, 440 A.2d 455, 463 (N.J. Super. Ct. App. Div. 1981)(finding at trial that Wolf's conduct, demolishing a former mercury plant, did not add more than a de minimis increment to the total mercury pollution, and noting that Wolf had not operated a mercury processing plant or dumped mercury, like the other defendants had).

Finally, Defendants' brief refers to ECF No. 1077, Plaintiffs' Motion for Modification of CMO 1 Regarding ARCOS Market Share Data and Amending Complaints, as support for its claim that "Plaintiffs themselves suggest that such small market share renders a distributor de minimis." Def Brief at 5. However, the request for 5% or more market share data was a compromise solution, not an admission. It was implemented to avoid Plaintiffs having to add hundreds or thousands of new Defendants (any Defendant who had manufactured or shipped even one opioid into the relevant counties) to their complaints. Of note, Plaintiffs were not limited to only naming Defendants with a 5% market share, other factors could result in naming defendants with lower market shares, such as having information about specific misconduct involving them or their opioids.

¹⁰¹ Contrary to Defendants' throwaway assertion in the conclusion of their brief, Plaintiffs have not asserted any "separate cause of action for punitive damages." Plaintiffs' complaints do, however, properly include factual allegations establishing a basis for punitive damages and do seek such damages in their Prayer for Relief. This is entirely proper under Ohio law. Defendants have offered the Court no valid basis for denying Plaintiffs that form of relief.

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